

**K172270 gammaCore-2**Dec 7, 2017  
132 days to decisionK172270 · Product code: **PKR** · Neurology  
Source: <https://www.510kdatabase.net/k172270/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-invasive Vagus Nerve Stimulator - Headache (PKR)
Date received	Jul 28, 2017
Decision date	Dec 7, 2017
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eletrocore, LLC</b>
Location	Basking Ridge, NJ, US
Contact	Mike Romaniw
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172270/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 31, 2026